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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,037	12/31/2001	Avigdor Levanon	10793/44	8494
26646	7590	03/08/2004	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			CANELLA, KAREN A	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/032,037	Applicant(s) LEVANON ET AL.	
	Examiner Karen A Canella	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-163 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-163 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:  
Claims 18-30, 32, 34-49, 51, 61, 68-72, 76-80, 82-86, 96, 103-107, 111-115, 117, 118 and 155 link inventions I-IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s) 18-30, 32, 34-49, 51, 61, 68-72, 76-80, 82-86, 96, 103-107, 111-115, 117, 118 and 155. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

- I Claims 18-51, 56-72, 76-86, 91-107, 111-118 and 155 drawn to antibodies capable of binding to cancer cells, antibodies coupled or complexed to anti-metastatic, anti-tumor or anti-leukemic agents, pharmaceutical compositions comprising said antibody wherein said antibodies are capable of inhibiting the growth of tumor cells, leukemia cells, metastatic cells, classified in class 530, subclasses 387.1 and 391.1..
- II. Claims 1-31, 34-49, 51, 52, 61, 68-72, 74, 76-80, 82-86, 87, 96, 103-107, 109 and 111-115, 117, 118 and 155, drawn to antibodies wherein said antibodies are capable of inhibiting inflammation and pharmaceutical compositions comprising antibodies coupled or complexed with anti-inflammatory agents, classified in class 530, subclasses 387.1 and 391.1.

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- III. Claims 18-30, 32, 34-49, 51, 53, 61, 68-72, 75-80, 82-86, 88, 96, 103-107, 110-115, 117, 118 and 155, drawn to antibodies wherein said antibodies are capable of inhibiting auto-immune disease and pharmaceutical compositions comprising antibodies coupled or complexed with anti-autoimmune agents, classified in class 530, subclasses 387.1 and 391.1.
- IV. Claims 18-30, 32, 34-49, 51, 54, 55, 61, 68-73, 76-80, 80-86, 89, 90, 96, 103-108, 111-115, 117, 118 and 155, drawn to antibodies wherein said antibodies are capable of inhibiting thrombosis and/or restinosis and pharmaceutical compositions comprising antibodies coupled or complexed with anti restinosis or anti-thrombosis agents, classified in class 530, subclasses 387.1 and 391.1.

Claims 119, 129, 136-141, 145-149, 151 and 152 link inventions V-VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s) 119, 129, 136-141, 145-149, 151 and 152. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

- V. Claims 119, 124-141, and 145-152, drawn to methods of inhibiting growth and or replication of tumor, metastatic or leukemia cells or increasing the susceptibility of tumor, or leukemia cells to damage by anticancer or anti-leukemia agents, classified in class 424, subclasses 130.1 and 178.1.
- VI. Claims 119, 120, 129, 136-141, 143, 145-149, 151 and 152 drawn to methods of inhibiting inflammation, classified in class 424, subclasses 130.1 and 178.1.

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- VII. Claims 119, 122, 123, 129, 136-142, 145-149, 151 and 152, drawn to methods of inhibiting restinosis and thrombosis, , classified in class 424, subclasses 130.1 and 178.1.
- VIII. Claims 119, 121, 129, 136-141, 144-149, 151 and 152, drawn to methods of inhibiting autoimmune diseases, classified in class 424, subclasses 130.1 and 178.1.
- IX. Claims 1-16, 153, 154, 156 and 157, drawn to epitopes, classified in class 530, subclass 806.
- X. Claims 158-163, drawn to polyclonal antibodies which cross-react with the variable light chain of antibody Y-1, compositions comprising said polyclonal antibodies complexed or conjugated to doxorubicin, diagnostic kits comprising said polyclonal antibodies, classified in class 530, subclass 389.1 and 391.1
- XI. Claim 17, drawn to polynucleotide encoding the epitopes of Group IX, classified in class 536, subclass 23.51.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV, and IX-XI are biologically and chemically distinct, made by and used in different methods and are therefore distinct inventions.

Inventions V-VIII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups I-IV and V-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see MPEP § 806.05(h)]. In the instant case the antibody multimers as claimed can be used in a materially different process such as producing an anti-idiotypic antibody, or can be used in an in vitro diagnostic assay.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

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examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Karen A. Canella, Ph.D.

Primary Examiner, Art Unit 1642

03/04/04

  
**KARENA. CANELLA PH.D**  
**PRIMARY EXAMINER**